POLICY AND COMMUNICATIONS BULLETIN
THE CLINICAL CENTER

Medical Administrative Series

M87-6 (rev.) 29 October 1999

MANUAL TRANSMITTAL SHEET

SUBJECT: Policy on Use of Investigational Drugs (FDA-approved IND) Brought into the Clinical Center by Patients for Therapeutic Use

1. Explanation of Material Transmitted: This issuance transmits the Clinical Center (CC) policy on the use of investigational drugs (FDA-approved IND) that are brought into the CC by patients for therapeutic use. The policy was reviewed by the Medical Executive Committee on 19 October 1999 and approved with minor changes for clarity.

2. Material Superseded: MAS No. M87-6 (rev.), dated 20 May 1997

3. Filing Instructions: Pharmacy Section

   Remove: No. M87-6 (rev.), dated 20 May 1997

   Insert: No. M87-6 (rev.), dated 29 October 1999

DISTRIBUTION

Physicians, Dentists and Other Practitioners Participating in Patient Care

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SUBJECT: Policy on Use of Investigational Drugs (FDA-approved IND) Brought Into the Clinical Center by Patients for Therapeutic Use

PURPOSE

This issuance sets forth the Clinical Center's (CC) policy on the use of investigational drugs (FDA-approved IND) that are brought into the CC by patients for therapeutic use. The policy defines the conditions under which such drug products may be used in the CC.

POLICY

Following are the conditions governing the use of investigational medications (FDA-approved IND) that are brought into the CC by patients for therapeutic use.

1. The attending physician or principal investigator must assume responsibility for the continued use and administration of the drug in the CC.

2. The agent must be identifiable by the Pharmacy Department or physician. It is incumbent upon the physician to obtain as much information as possible about the drug product, why the drug is needed prior to its continued use, and document that the drug will not affect the outcome of the study.

3. Prior to administration of the drug the physician should document in the progress notes of the patient's medical record that he/she advised the patient that the drug has not been approved by an NIH Institutional Review Board and the CC; the limits of the CC's knowledge about the safety and efficacy of the medication in general; the identity and purity of the patient's supply in particular; and the inability of the CC to refill the prescription once the patient's supply is expended. If the patient indicates that he/she intends to continue using the drug, this should also be recorded.

4. The medication order should be entered into the MIS with the message, "patient's own supply."

5. The Pharmacy Department will register the drug prior to its administration and affix an auxiliary label to it bearing the words:

"Pharmacy Department"
PDS control number
Source: Patient's name
Status: "Investigational Drug Brought by Patient"

The drug product will not be relabeled, nor will it be registered as an investigational drug. It will be registered by PDS and recorded on a separate log for informational purposes only. Although the Pharmacy Department may have registered the drug and affixed an auxiliary label to it, this does not assure the drug's identity and purity.